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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/394,020	09/10/1999	CARMEN V. PEPICELLI	HUIP-P01-032	3626

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EXAMINER

ANDRES, JANET L

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 09/03/2003

40.

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/394,020

Applicant(s)

PEPICELLI ET AL.

Examiner

Janet L. Andres

Art Unit

1646

--Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 06 August 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_

Claim(s) objected to: \_\_\_\_\_


Claim(s) rejected: 1,2,4,5 and 24-28.Claim(s) withdrawn from consideration: 22,34 and 35.

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
10. ☐ Other: \_\_\_\_\_

Continuation of 3. Applicant's reply has overcome the following rejection(s): Applicant's amendment overcomes the rejection of claims 1,2,4,5, and 24-28 under 35 U.S.C. 112, first paragraph, as introducing new matter and as lacking enablement.

Continuation of 5. does NOT place the application in condition for allowance because: Applicant's amendment results in the reinstatement of the rejection of the claims under 35 U.S.C. 103(a) as unpatentable over Fujita et al. or Fujita et al. in view of the '786 patent, as was indicated in paragraph 3 of the office action of paper no. 38. Applicant cites MPEP 2131 with respect to anticipation of claims, and argues that Fujita et al. fails to teach a method for inhibiting growth of cells by influencing the surrounding cells. Applicant further argues that the method of Fujita et al. would not allow the determination of whether hedgehog expression was decreased in surrounding cells. Applicant additionally argues that Fujita et al. does not teach in vivo methods. Applicant concludes that Fujita et al. does not anticipate the instant claims and that the rejection under 35 U.S.C. 103(a) was rightly withdrawn. Applicant's arguments have been fully considered but have not been found to be persuasive.

The claims were not rejected as anticipated by Fujita et al. Anticipation falls under 35 U.S.C. 102. The claims were rejected under 35 U.S.C. 103(a) as unpatentable over Fujita et al. or Fujita et al. in view of the '786 patent. The standard for 35 U.S.C. 103(a) is obviousness, not anticipation. As stated in the office actions of paper nos. 36 and 38, it would be obvious to one of ordinary skill in the art to use hedgehog antibodies to inhibit the growth of lung tumor cells by antagonizing hedgehog. Based on the teachings of Fujita et al. that inhibition of hedgehog results in inhibition of the growth of cells derived from lung cancer, one of ordinary skill would expect such an approach to be successful. The claims now recite inhibition of surrounding cells (it is noted, again, that hedgehog function, rather than expression, is what would be expected to be inhibited; Applicant provides no teachings to indicate that hedgehog signalling affects its own expression). While Fujita et al. does not, as Applicant states, teach methods of affecting surrounding cells, such effects would necessarily result from the method rendered obvious by Fujita et al. Fujita et al. renders it obvious to treat lung cancer with hedgehog antagonists, and this treatment would also affect the surrounding cells, regardless of whether such effects were recognized. Similarly, treatment of surrounding cells, as currently claimed by Applicant, would necessarily affect lung cancer cells and thus encompass the method rendered obvious by Fujita et al. Thus Applicant's amendment is not sufficient to overcome the rejection under 35 U.S.C. 103(a).

  
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